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## EUROPEAN PATENT APPLICATION

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### (54) Solution based methacholine formulations

(57) The present invention provides inhalable solution based formulations of methacholine that are stable, sterile and ready-to-use. Also provided are methods for preparing the ready-to-use methacholine formulations.

The formulations are useful in methacholine challenge testing for assessment of airway hyper-responsiveness in a subject.



DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	A61K31/221 A61P11/00 A61P11/06 G01N30/00 G01N33/00
X	WATSON, B.L., CORMIER, R.A. AND HARBECK, R.J.: "Effect of pH on the stability of methacholine chloride in solution" RESPIRATORY MEDICINE, vol. 92, March 1998 (1998-03), pages 588-592, XP009048090 the whole article, particularly page 589, left-hand column, line 12 to right-hand column, line 15, table 1, discussion	1-6, 12, 22-24	A61K31/221 A61P11/00 A61P11/06 G01N30/00 G01N33/00
X	BONTE, F. ET AL.: "Contribution pharmaceutique à l'exploration de l'hyperréactivité bronchique non spécifique" ANN PHARM FR, vol. 58, 2000, pages 165-169, XP009048091 * page 166, right-hand column, line 4 - page 167, right-hand column, line 3; figure 3 *	1-3, 7, 9, 12-14, 22-24	
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		-/-	
The present search report has been drawn up for all claims			
5	Place of search	Date of completion of the search	Examiner
	Munich	30 August 2005	Venturini, F
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ..... & : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			



DOCUMENTS CONSIDERED TO BE RELEVANT									
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)						
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Y	US 2004/042970 A1 (BASU SUJIT K ET AL) 4 March 2004 (2004-03-04) * example 3 * -----	1,22-24							
A	WO 00/62819 A (1355540 ONTARIO INC; SLUTSKY, ARTHUR; ZAMEL, NOE; WULFFHART, HAROLD) 26 October 2000 (2000-10-26) * the whole document * -----	1-24							
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Y	WOODMAN, T. F. ET AL.: "Determination of methacholine chloride by ion-pair high-pressure liquid chromatography" JOURNAL OF LIQUID CHROMATOGRAPHY, vol. 5, no. 7, 1982, pages 1341-1348, XP009053054 * page 1344, line 7 - page 1345, line 17 * -----	25-28	TECHNICAL FIELDS SEARCHED (Int.Cl.7)						
A	ROSENFELD, J. ET AL.: "Gas chromatographic determination of methylcholine chloride in pharmaceutical preparations" JOURNAL OF CHROMATOGRAPHY, vol. 287, 1984, pages 433-437, XP001207507 * the whole document * -----	25-28							
<p>5 The present search report has been drawn up for all claims</p> <table border="1"> <tr> <td>Place of search</td> <td>Date of completion of the search</td> <td>Examiner</td> </tr> <tr> <td>Munich</td> <td>30 August 2005</td> <td>Venturini, F</td> </tr> </table> <p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone  Y : particularly relevant if combined with another document of the same category  A : technological background  O : non-written disclosure  P : intermediate document</p> <p>T : theory or principle underlying the Invention  E : earlier patent document, but published on, or after the filing date  D : document cited in the application  L : document cited for other reasons  .....  &amp; : member of the same patent family, corresponding document</p>				Place of search	Date of completion of the search	Examiner	Munich	30 August 2005	Venturini, F
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Munich	30 August 2005	Venturini, F							

**CLAIMS INCURRING FEES**

The present European patent application comprised at the time of filing more than ten claims.

- Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):
  
- No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

**LACK OF UNITY OF INVENTION**

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

- All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
  
- As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.
  
- Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
  
  
- None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:



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**LACK OF UNITY OF INVENTION  
SHEET B**

Application Number  
EP 04 25 5015

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

**1. claims: 1-24**

formulation containing methacholine chloride in a buffer  
solution having a pH between 4 and 5  
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**2. claims: 25-28**

method for determining the amount of methacholine chloride  
in a sample  
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ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.

EP 04 25 5015

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EPO file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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